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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,186	09/21/2007	Rudolf Brenneisen	8588-US	3801
74476 7590 07/16/2010 Nestle HealthCare Nutrition 12 Vreeland Road, 2nd Floor, Box 697 Florham Park, NJ 07932				
EXAMINER				
HA, JULIE				
ART UNIT		PAPER NUMBER		
1654				
NOTIFICATION DATE		DELIVERY MODE		
07/16/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/580,186

Applicant(s)

BRENNEISEN ET AL.

Examiner

JULIE HA

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-24, 26-33 and 36-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 29-33, 36, 37 and 41-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 12-24, 26-28, 38-40 and 45-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Amendment after Non-final office action filed on May 07, 2010 is acknowledged. Claims 11, 25, 34-35 have been cancelled. Claims 1-10, 12-24, 26-33 and 36-47 are pending in this application. Applicant elected with traverse of Group 3 and the election of species γ -L-glutamyl-S-(trans-l-propenyl)-L-cysteine sulfoxide as the γ -glutamyl peptide, skim milk powder as the calcium source, maltodextrins as the carbohydrate, omega-6 polyunsaturated fatty acid source as the fat source, soy bean derived protein as the nitrogen source, Vitamin A as the vitamin, potassium as the mineral, gum Arabic as the fiber, vegetable flavors as the flavor, and Allium cepa as the Allium, and further elected γ -glutamyl-alkyl-cysteine sulfoxide as the γ -glutamyl-peptide, osteoporosis as the disease, calcium chloride as the calcium source, carbohydrate as the energy source, maltodextrins as the carbohydrate, vitamin D as the vitamin on November 02, 2009. The traversal was not found persuasive, and the restriction was deemed proper and was made FINAL in the previous office action. There were inconsistencies between the elected species filed on August 11, 2009 and November 02, 2009. For the purpose of this examination, the election of species filed on November 02, 2009 was examined. Search was conducted on the elected species, and prior art was found. A prior art WO 98/50054 A1 teaches the other nonelected species. Therefore, election of species was withdrawn in the previous office action. Claims 1-9, 33, 36-37 and 41-44 are withdrawn from further consideration, pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 29-32, previously drawn to a g-L-glutamyl-trans-S-1-propenyl-L-cysteine sulfoxide by fractionation of an

hydrophilic, ethanolic extract of *Allium* have been amended to method claims.

Therefore, Claims 29-32 are hereby withdrawn from consideration, as being drawn to nonelected invention. Claims 10, 12-24, 26-28, 38-40 and 45-47 are examined on the merits in this office action.

After further review, a non-final rejection follows below.

Withdrawn Objection and Rejections

1. Objection to claims 34-35 as being improper dependent form for failing to further limit the subject matter of a previous claim is hereby withdrawn in view of Applicant's cancellation of claims 34-35.
2. Rejection of claims 10, 23-24, 27 and 45 under 35 U.S.C. 102(b) as being anticipated by Blatt et al (US Patent No. 6,270,803), is hereby withdrawn in view of Applicant's amendment to the claims.
3. Rejection of claims 10-12, 22-26, 29-32, 34-35, 38 and 45 under 35 U.S.C. 102(b) as being anticipated by Kuttan et al (Biochemistry, 1974, 13(21): 4394-4400, filed with IDS), is hereby withdrawn in view of Applicant's amendment to the claims.
4. Rejection of claims 10-32, 34-35, 38-40, and 45-47 under 35 U.S.C. 102(b) as being anticipated by Muhlbauer (WO 98/50054, filed with IDS), is hereby withdrawn in view of Applicant's amendment to the claims.

New Rejection

35 U.S.C. 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 10, 12-24, 26-28, 38-40 and 45-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Muhlbauer (WO 98/50054, filed with IDS) as being evidenced by Kuttan et al (Biochemistry, 1974, 13(21): 4394-4400, filed with IDS) and as evidenced by Wettli et al (J. Agric. Food Chem., 2005, 53(9): 3408-3014, abstract only provided. Full reference requested).

7. Muhlbauer reference teaches a nutritional composition comprising all of the active components of instant claims (see throughout the reference, Claims 5-20), meeting the limitation of instant claims 10 in part, 38 and 45. The reference teaches that the nutritional or pharmaceutical compositions containing a plant extract or concentrate selected from the group consisting of allium, eruca, petroselinum and brassica extracts or concentrates (see abstract and p. 2, last paragraph). The reference teaches that the composition is useful for the treatment of diseases or conditions which are characterized by increased bone resorption, osteoporosis (see abstract). The reference teaches that the term allium refers to the genus allium and includes for example any member of the botanical species *Allium cepa* (onion), *Allium ascalonium* and so on, and

indicates that the preferred extract is from *Allium cepa* (see p. 3, 2nd paragraph, see p. 4, 6th paragraph). The onion extracts and concentrates are prepared from the whole eatable part of the vegetable (see p. 3, 3rd paragraph). The reference teaches that the extract and concentrates of the above-mentioned plants or vegetables may be in liquid form or in solid form such as in granulate or powder form (see p. 5, 1st paragraph), meeting the limitation of claims 22-23. The reference teaches that suitable methods of obtaining extracts of the above-mentioned plants or vegetables are known in the art...by extracting the fresh cut or dried plants or vegetables or the respective roots, fruits or seeds thereof for example with water or with one or more food grade solvents or with a mixture of water and one or more food grade solvents...ethanol (see p. 5, 3rd paragraph). Further, Example 4 at page 16, explicitly teaches ethanol/water extraction. As evidenced by Kuttan et al, γ -L-glutamyl-S-(trans-l-propenyl)-L-cysteine sulfoxide isolated from sandal (*Santalum album* L.) is the same as the protein isolated from onion (*Allium cepa*) (see abstract). The reference teaches that γ -L-glutamyl-S-(trans-l-propenyl)-L-cysteine sulfoxide is in aqueous solutions, water (see p. 4396, right column, "CD Absorption"). Therefore, the ethanolic extract of *allium cepa* of the reference would inherently comprise the γ -L-glutamyl-trans-S-l-propenyl-L-cysteine sulfoxide of the instant claims. The reference teaches that the extract may be used in liquid form, particularly in aqueous form, or in solid form, granulate or powder form. If the extracts in liquid form, it has a solid contents of for example from 1 to 25% by weight, preferably from 2 to 20% by weight and most preferred from 2 to 15% by weight (see p. 6, 2nd paragraph).

The reference teaches that the subject to be treated is an adult person a satisfactory inhibitory effect on bone resorption is, in general obtained with compositions formulated to allow a daily administration of 0.1 to 20 grams, preferably 0.2 to 15 grams and most preferred 0.4 to 10 grams of allium, petroselinum, brassica and/or eruca concentrate or extract (see p. 6, 2nd paragraph). The reference further teaches that suitable nutritional compositions comprising the plant/vegetable extracts comprise at least one (a) plant/vegetable extract or concentrate from allium, (b) a calcium source, and (c) at least one energy source selected from carbohydrate, fat and nitrogen sources, and Vitamin D (see p. 6, last paragraph, claim 5), meeting the limitation of instant claims 10, 12, 38 and 45. Since the nutritional composition comprises the same active compound, this would inherently have the same functionality and characteristics of instant claims 38 and 45. The reference teaches that from approximately 0.1 to 40%, preferably from approximately 3 to 25% of plant/vegetable extract or concentrate component (a) (see p. 6, last paragraph); calcium source such as calcium chloride or skim milk and the calcium source (b) is in one unit dosage from about 100 mg to 1000 mg, preferably 200 mg to 700 mg or from approximately 1 to 60 %, preferably from approximately 5 to 50% of calcium component (b) (see p. 7, 1st and 2nd paragraph); suitable carbohydrate sources include for example maltodextrins, starch, lactose, glucose (see p. 7, 3rd paragraph); suitable fat sources include omega-6 polyunsaturated fatty acid (see p. 7, 4th paragraph); suitable nitrogen sources such as soybean derived proteins (see p. 8, 4th paragraph), meeting the limitation of claims 14-17 and 19. The reference teaches that the nutritional composition comprise from approximately 0.1 % to

98.9%, preferably from approximately 1 to approximately 95% of energy source (p. 9, 1st paragraph), further meeting the limitation of claim 19. The reference teaches that the carbohydrate source provides for 30 to 70% of the total energy supply, the nitrogen source for 5 to 45 %, and the fat source for 0.1 to 15% of the total energy supply (see p. 9, 2nd paragraph), meeting the limitation of instant claim 18. Further, the reference teaches that the nutritional formulation may comprise other nutritionally acceptable components such as vitamins (see p. 10, 1st paragraph), meeting the limitation of instant claim 20. The reference teaches that the supplement comprises energy sources in an amount supplying from 50 to 1500 kcal/day (see p. 11, 2nd paragraph, see claim 16), meeting the limitation of instant claim 21. The reference teaches that the nutritional formulation is formulated in any form suitable for enteral administration, in aqueous form or in powder or granulate form, whereby the powder or granulate is conveniently added to water prior to use (see p. 11, 1st and 2nd paragraphs), meeting the limitation of claims 24 and 26. Additionally, the reference teaches dragee, table, capsule, sachet or suppository compositions (see p. 12, 3rd paragraph, see claim 20), meeting the limitation of instant claims 27-28.

Furthermore, the reference teaches that 250 mg freeze-dried onion extract are obtained for each g of dry whole onion, and the onion extract (0.017, 0.17, 1.7 mg onion extract/ ml medium) inhibited osteoclast-mediated resorption (see column 12, lines 1-9). As evidenced by Wetli et al, the molecular mass of gamma-L-glutamyl-trans-S-1-propenyl-L-cysteine sulfoxide is 306 Da (see abstract). The onion extract at 0.017 mg/ml would yield 55.5 μ M effective dose; at 0.17 mg/ml would yield 555.5 μ M effective

dose; at 1.7 mg/ml would yield 5.55 mM effective dose, Meeting the limitation of instant claims 39-40 and 46-47. Therefore, the reference anticipates instant claims 10, 12-24, 26-28, 38-40 and 45-47.

Conclusion

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/
Examiner, Art Unit 1654